



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,432	01/31/2002	Thomas F. Smith	07039-246001	5103

26191 7590 07/23/2004

FISH & RICHARDSON P.C.
3300 DAIN RAUSCHER PLAZA
60 SOUTH SIXTH STREET
MINNEAPOLIS, MN 55402

EXAMINER

HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
----------	--------------

1637

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

31A.

Office Action Summary**Application No.**

10/066,432

Applicant(s)

SMITH ET AL.

Examiner

Kenneth R Horlick

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-136 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 73-78, 116-119 and 131-134 is/are allowed.
- 6) ☒ Claim(s) 54-70, 79, 81-115, 120, 122-130, 135, 136 is/are rejected.
- 7) ☒ Claim(s) 71, 72, 80 and 121 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/19/04; 6/28/04</u> (2 pages) | 6) <input type="checkbox"/> Other: _____ |

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 54-70 are rejected under 35 U.S.C. 102(a) as being anticipated by Espy et al. (J. Clin. Micro. Feb 2000).

Espy et al. clearly teach the claimed methods; see entire reference on pages 795-799. This is a reference to "others" as besides the four instant inventors, Espy et al. names three other authors.

2. In the response filed 05/12/04, it is argued that Espy et al. does not qualify as prior art under 35 U.S.C. 102(a) based on the date of acceptance for publication, which predates the date of publication, establishing that the inventors were in possession of the claimed invention prior to the publication date. However, this is not persuasive because, as noted in the rejection, Espy et al. is in fact a reference to "others". Applicants are directed to M.P.E.P. 706.02(b) for possible ways of overcoming this rejection, such as through submission of a "Katz-type" declaration showing that the reference invention is not by "another".

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (9 or (g) prior art under 35 U.S.C. 103(a).

Claims 79 and 81-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg et al. (US 5,846,706) in view of Wittwer et al. (US 6,140,054), and further in view of Heller (US 4,824,776).

These claims are drawn to methods comprising detection of HSV by PCR amplification of TK nucleic acid sequences, and detection using two FRET-labeled oligonucleotide probes which hybridize adjacently on the amplified target nucleic acid. The second TK probe comprises SEQ ID NO:10.

Greenberg et al. disclose the detection of HSV using PCR and hybridization detection probes. The primers and probes target both the polymerase and TK genes,

as required in the claims. This patent further discloses probes capable of distinguishing HSV-I from HSVQ. See especially column 11, line 29 to column 12, line 38 and Example 2 in columns 13-14.

Greenberg et al. do not teach PCR combined with a detection system comprising two FRET-labeled oligonucleotide probes which hybridize adjacently on the amplified target nucleic acid; nor do they disclose a probe comprising SEQ ID NO:10.

Wittwer et al. disclose PCR combined with detection via two FRET-labeled oligonucleotide probes which hybridize adjacently on the amplified target nucleic acid, as well as melting temperature analysis to distinguish among variant target sequences (see column 2, lines 39-52; column 3, lines 19-40; column 4, lines 19-41; columns 11-19).

Heller discloses the use of an HSV TK detection probe comprising SEQ ID NO:10 (see displacer probe in column 13, at line 6).

One of ordinary skill in the art would have been motivated to modify the HSV detection method of Greenberg et al. by using two FRET-labeled oligonucleotide probes which hybridize adjacently on the amplified target nucleic acid because Wittwer et al. taught that such probe pairs provided an advantageous detection means. The skilled artisan would have been further motivated to use an HSV TK probe comprising SEQ ID NO:10 in the method of Greenberg et al. as modified by Wittwer et al. because Heller disclosed such a probe and its advantageous use in HSV detection assays. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

4. Claims 106-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg et al. (US 5,846,706) in view of Wittwer et al. (US 6,140,054), and further in view of Espy et al.

These claims are drawn to methods comprising detection of HSV by PCR amplification of DNA polymerase nucleic acid sequences, and detection using two FRET-labeled oligonucleotide probes which hybridize adjacently on the amplified target nucleic acid. The probes comprise sequences from SEQ ID NO:3-6.

Greenberg et al. disclose the detection of HSV using PCR and hybridization detection probes. The primers and probes target both the polymerase and TK genes, as required in the claims. This patent further discloses probes capable of distinguishing HSV-I from HSVQ. See especially column 11, line 29 to column 12, line 38 and Example 2 in columns 13-14.

Greenberg et al. do not teach PCR combined with a detection system comprising two FRET-labeled oligonucleotide probes which hybridize adjacently on the amplified target nucleic acid; nor do they disclose probes comprising SEQ ID NO:3-6.

Wittwer et al. disclose PCR combined with detection via two FRET-labeled oligonucleotide probes which hybridize adjacently on the amplified target nucleic acid, as well as melting temperature analysis to distinguish among variant target sequences (see column 2, lines 39-52; column 3, lines 19-40; column 4, lines 19-41; columns 11-19).

Espy et al. disclose the use of HSV detection probes comprising SEQ ID NO:3-6.

One of ordinary skill in the art would have been motivated to modify the HSV detection method of Greenberg et al. by using two FRET-labeled oligonucleotide probes which hybridize adjacently on the amplified target nucleic acid because Wittwer et al. taught that such probe pairs provided an advantageous detection means. The skilled artisan would have been further motivated to use HSV probes comprising SEQ ID NO:3-6 in the method of Greenberg et al. as modified by Wittwer et al. because Espy et al. disclosed such probes and their advantageous use in HSV detection assays. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

5. Claims 120 and 122-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg et al. (US 5,846,706) in view of Livak et al., and further in view of Heller.

These claims are drawn to methods comprising detection of HSV by PCR amplification of TK nucleic acid sequences, and detection using a probe comprising two labels enabling FRET detection. The probe comprises SEQ ID NO:10.

Greenberg et al. disclose the detection of HSV using PCR and hybridization detection probes. The primers and probes target both the polymerase and TK genes, as required in the claims. This patent further discloses probes capable of distinguishing HSV-I from HSVQ. See especially column 11, line 29 to column 12, line 38 and Example 2 in columns 13-14.

Greenberg et al. do not teach PCR combined with a detection system comprising

a probe having two labels enabling FRET detection; nor do they disclose a probe comprising SEQ ID NO:10.

Livak et al. disclose PCR combined with detection via a probe having two labels enabling FRET detection (see especially Figure 1 on page 358).

Heller discloses the use of an HSV TK detection probe comprising SEQ ID NO:10 (see displacer probe in column 13, at line 6).

One of ordinary skill in the art would have been motivated to modify the HSV detection method of Greenberg et al. by using a probe having two labels enabling FRET detection because Livak et al. taught that such a probe provided an advantageous detection means. The skilled artisan would have been further motivated to use an HSV TK probe comprising SEQ ID NO:10 in the method of Greenberg et al. as modified by Livak et al. because Heller disclosed such a probe and its advantageous use in HSV detection assays. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

6. Claims 110-115 and 122-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg et al. (US 5,846,706) in view of Livak et al., and further in view of Espy et al.

These claims are drawn to methods comprising detection of HSV by PCR amplification of TK nucleic acid sequences, and detection using a probe comprising two labels enabling FRET detection. The probes comprise SEQ ID NO:1-6.

Greenberg et al. disclose the detection of HSV using PCR and hybridization

detection probes. The primers and probes target both the polymerase and TK genes, as required in the claims. This patent further discloses probes capable of distinguishing HSV-I from HSVQ. See especially column 11, line 29 to column 12, line 38 and Example 2 in columns 13-14.

Greenberg et al. do not teach PCR combined with a detection system comprising a probe having two labels enabling FRET detection; nor do they disclose probes comprising SEQ ID NO:1-6.

Livak et al. disclose PCR combined with detection via a probe having two labels enabling FRET detection (see especially Figure 1 on page 358).

Espy et al. disclose the use of HSV detection probes comprising SEQ ID NO:1-6.

One of ordinary skill in the art would have been motivated to modify the HSV detection method of Greenberg et al. by using a probe having two labels enabling FRET detection because Livak et al. taught that such a probe provided an advantageous detection means. The skilled artisan would have been further motivated to use HSV probes comprising SEQ ID NO:1-6 in the method of Greenberg et al. as modified by Livak et al. because Espy et al. disclosed such probes and their advantageous use in HSV detection assays. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

7. Claims 127-130, 135, and 136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenberg et al. (US 5,846,706) in view of Higuchi et al., and further in view of Espy et al.

These claims are drawn to methods comprising detection of HSV by PCR amplification of polymerase nucleic acid sequences, and detection using a nucleic acid binding dye. Amplification primers comprise SEQ ID NO:1 and 2.

Greenberg et al. disclose the detection of HSV using PCR and hybridization detection probes. The primers and probes target both the polymerase and TK genes, as required in the claims. This patent further discloses probes capable of distinguishing HSV-I from HSVQ. See especially column 11, line 29 to column 12, line 38 and Example 2 in columns 13-14.

Greenberg et al. do not teach PCR combined with a detection system comprising a binding dye; nor do they disclose SEQ ID NO:1 and 2.

Higuchi et al. disclose PCR combined with detection via a binding dye (see pages 413-416).

Espy et al. disclose the use of HSV detection probes comprising SEQ ID NO:1 and 2.

One of ordinary skill in the art would have been motivated to modify the HSV detection method of Greenberg et al. by using a nucleic acid binding dye because Higuchi et al. taught that such a dye provided an advantageous detection means. The skilled artisan would have been further motivated to use HSV probes comprising SEQ ID NO:1 and 2 in the method of Greenberg et al. as modified by Livak et al. because

Art Unit: 1637

Espy et al. disclosed such probes and their advantageous use in HSV detection assays.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

8. Claims 71, 72, 80, and 121 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 73-78, 116-119, and 131-134 are allowable.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1637

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kenneth R Horlick
Primary Examiner
Art Unit 1637

07/20/04